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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,599	10/03/2000	Leigh T Canham	124-796	1219

23117 7590 05/06/2003

NIXON & VANDERHYE, PC  
1100 N GLEBE ROAD  
8TH FLOOR  
ARLINGTON, VA 22201-4714

EXAMINER
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WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/06/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 134-143 is/are pending in the application.
- 4a) Of the above claim(s) 34,35,54-57,59-71,76-95 and 103-108 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 134-143 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of amendment, request for extension of time (granted), information disclosure statement and response all filed 2-10-03 is acknowledged. Claims 34-35, 54-57, 59-71, 76-95, 103-108, and 113-133 have been canceled and new claims 134-143 have been added.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-10-03 has been entered.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**4. Claims 134-139 and 142-143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canham et al (WO 97/06101; hereafter '101).**

5. '101 teaches resorbable porous polycrystalline silicon implants that release active agents such as calcium. The porosity of the implants is within the instant claimed ranges. '101 does not distinctly teach that the implants are to erode for an interval between one month and one year. However, it would have been obvious to one skilled in the art at the time of the invention to tailor the resorption profile of the implants on the basis of the teachings of '101 that rate of resorption of the implant is based upon the porosity of the silicon and the motivation of providing an active agent for a particular period of time.

#### ***Response to Arguments***

6. Applicant's arguments filed 2-10-03 as applied to the new rejection have been fully considered but they are not persuasive. Applicant argues that while '101 teaches porosity of the implant within the instant range, it would not have been obvious to one skilled in the art at the time of the invention to administer active agent with the implant since '101 teaches formation of a barrier over the implant. Applicant asserts that this

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barrier "could prevent delivery of the beneficial substance over the desired time interval" and would therefore discourage use for drug delivery. As mentioned in the Final Office Action of 10-22-02, Paper # 9, '101 only refers to reduction of the physiological effects of the silicon and there is no teaching that effects no longer occur. Furthermore, Applicant has not provided any evidence or data attesting that an active agent would not permeate through such a barrier. Therefore, Applicant's comments are deemed speculative.

7. **Claims 140-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canham et al (WO 97/06101; hereafter '101) in view of Santini, Jr. et al (5,797,898; hereafter '898).**

8. '101 is relied upon for all that it teaches as stated previously. '101 does not teach reservoir(s) with a door made of silicon that is corroded.

9. '898 teaches degradable multi-reservoir implants with doors for computer controlled drug release.

10. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the implants of '101 in the fashion of '898 with the motivation of providing controlled, extended drug release.

### ***Conclusion***


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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
May 2, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600